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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/478,222 01/05/00 GARVEY

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025270
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HM12/0629

EXAMINER

CELSA, B

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

Office Action Summary

Application No.
09/478,222

Applicant(s)
Garvey et al.

Examiner
Bennett Celsa

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-69 is/are pending in the application.
- 4a) Of the above, claim(s) 35-60 and 66-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

Status of the Claims

Claims 35-69 are currently pending.

Claims 61-65 are under consideration.

Claims 35-60 and 66-69 are withdrawn from consideration as being directed to a non-elected invention.

Election/Restriction

1. Applicant's election with traverse of Group VI (new claims 61-65) and the election of S-nitrosoglutathione as the elected species of S-Nitrosothiol compound in Paper No. 5 is acknowledged.

The traversal is on the ground(s) that the grandparent and great grandparent applications received different restrictions. This is not found persuasive for all of the following reasons: the present application is not drawn to the same subject matter of the (great) grandparent applications. The (great)grandparent applications were drawn to compositions containing combinations of components and their use to treat male impotence; whereas the present application addresses the specific use of a single compound to treat impotence (e.g. sydnonimine, 2-hydroxy-nitrosohydrazine, E-alkyl-2-E ... hexene amines). Additionally, the grandparents' compositions contain additional components (e.g. of Formula II or III) which are not present in the present application. Further, the present application is not related to the grandparent applications by divisional status, nor is the present applications subject to lack of unity practice.

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Still further, as discussed in the restriction requirement, and not rebutted by applicant, Inventions I-VII are directed to methods which require the use of bioactive compounds which differ in chemical structures and/or expectant properties and/or method of syntheses; which would necessitate different and separately burdensome manual/computer structure, bibliographic and classification searches. To the extent that applicant argues that these methods have the same classification, Applicant is referred to pages 2-3 of the Office action for restriction which indicates that there is a different classification for Groups I-VI since these groups clearly fall in different subclasses. Additionally, as pointed out in the restriction/election requirement, the Groups encompass the use of compounds which are structurally distinct such that the methods would be expected to have different modes of operation, different functions, and/or different effects. With regard to other U.S. Patents cited by applicant as not restricting out NO donating compounds, it is noted that each application is examined on its own merits

Applicant further argues that a lack of species was not required in the grandparent applications. Upon review of the restriction requirements for both 08/714,313 and 08/595,732 applications, applicant appears to be misguided in this respect, since an election of species requirement was made in both grandparent applications. Applicant further argues that it is not burdensome for the Examiner to search Groups I-VI since these groups do not have a separate classification in the art; do not have a separate status in the art; and do not require a different field of search. Applicant is again referred to pages 2-3 of the Office action for restriction which indicates that there is a different classification for Groups I-VI since these groups clearly fall in

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different subclasses. Additionally, as discussed in the restriction on page 3, different and separately burdensome manual and computer structure and bibliographic searches are further required.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 35-60 and 66-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 61-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (e.g. NEW MATTER REJECTION).

In the Preliminary Amendment (filed 1/5/200) claims 61-65 addressing methods for treating female impotence by administering S-nitrosothiols were newly added. Although having support for treating "female sexual dysfunctions" (e.g using S-nitrosothiols) the original specification and original claims do not support treating "female impotence" as presented in new claims 61-65 of the Preliminary Amendment. It is noted that an amendment filing along with the filing of an application (as in the present Preliminary Amendment) *does not enjoy* the status as

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part of the original disclosure in an application filed under 37 CFR 1.53(b) unless it is specifically referred to in the oath or declaration filed therewith (e.g. see MPEP 608.04b). IN the present instance, the oath or declaration fails to specifically refer to the Preliminary Amendment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 (10/96: filed 8/93).

Stamler et al teach the that S-nitrosothiols achieve both smooth muscle and and blood vessel relaxation (e.g. *vasodilation*) and are useful to treat male sexual dysfunction (e.g. impotency) by administration (E.g. topical) of S-nitrosothiol compounds, including the use of S-nitrosylated amino acids and peptides (e.g. S-nitrosoglutathione) which are clearly within the scope of the presently claimed invention (e.g. see Stamler et al. at Abstract; col. 1, lines 20-37; bottom of col. 2- top of col. 4; col. 4, lines 45-55); col. 11; patent claims 1-3, 14-16, 20-23).

Although teaching the use of S-nitrosothiols to treat impotence in males, the Stamler reference differs from the presently claimed invention in failing to teach the use of the same agent (e.g. S-nitrosothiols) to treat impotence in females.

The Gioco et al. Patent discloses that male and female impotency would be expected to be treated similarly (e.g. by use of vasodilating agents) since the erectile response: is common to both males and females (e.g see col. 1, 20-30), shares common characteristics (E.g. result of blood engorgement of erectile tissues in response to sexual stimulation) and is treated similarly e.g. with the administration (e.g. topical) of *vasodilating* agents (e.g. see col. 1, lines 10-20; col. 3, lines 45-65; col. 4-7).

Thus, the Gioco patent reference provides one of ordinary skill in the art with motivation to utilize S-nitrosothiols to treat female impotency in the same manner as in the treatment of

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males as disclosed in Stamler, since Gioco teaches that the erectile response in males and females is similar and amenable to similar treatments including the utilization of vasodilating agents which would encompass S-nitrothiols.

Accordingly, it would have been obvious to one of ordinary skill at the time of applicant's invention to use (e.g. topical administration) S-nitrosothiol compounds (e.g. S-nitrosyl-glutathione) to treat female impotence in the manner disclosed in the Stamler reference in light of the Gioco reference teaching.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 61-65 are provisionally rejected under the judicially created doctrine of provisional obviousness-type double patenting as being unpatentable over the pending claims (e.g. claims 8-11) of copending Application No. 09/354,424 in view of Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 (as discussed above and incorporated by reference).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '424 teach a method of treating female sexual dysfunction using S-nitrosothiols. To the extent that the '424 claims fail to teach treatment of a species of female sexual dysfunction (E.g. female impotence) as presently claimed, treating female impotency using S-nitrosothiols would have been obvious in view of Stamler and Gioco which teach that S-nitrosothiols treat male impotence (e.g. Stamler) to which female impotence would be similarly treated in view of Gioco's teaching that female and male impotence is amenable to the same treatment (e.g. especially using vasodilating agents such as S-nitrosothiols).

8. Claims 61-65 are provisionally rejected under the judicially created doctrine of provisional obviousness-type double patenting as being unpatentable over the pending claims (e.g. claims 20-66, especially claims 20, 31-33) of copending Application No. 09/280,540 in view of Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 (as discussed above and incorporated by reference).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '540 teach a method of treating female sexual dysfunction using S-nitrosothiols. To the extent that the '540 claims fail to teach treatment of a species of female sexual dysfunction (E.g. female impotence) as presently claimed, treating female impotence using S-nitrosothiols would have been obvious in view of Stamler and Gioco which teach that S-nitrosothiols treat male impotence (e.g. Stamler) to which female impotence would be treated

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similarly in view of Gioco's teaching that female and male impotence is amenable to the same treatment (e.g. especially using vasodilating agents such as S-nitrosothiols)..

9. Claims 61-65 are provisionally rejected under the judicially created doctrine of provisional obviousness-type double patenting as being unpatentable over the pending claims (e.g claims 35-56, especially claims 41 and 44-46) of copending Application No. 09/306,809 in view of Stamler et al. US Pat. No. 5,380,758 (1/10/95) and Gioco et al., U.S. Pat. No. 5,565,466 (as discussed above and incorporated by reference).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '809 teach a method of treating female sexual dysfunction using S-nitrosothiols. To the extent that the '809 claims fail to teach treatment of a species of female sexual dysfunction (E.g. female impotence) as presently claimed, treating female impotence using S-nitrosothiols would have been obvious in view of Stamler and Gioco which teach that S-nitrosothiols treat male impotence (e.g. Stamler) to which female impotence would be treated similarly in view of Gioco's teaching that female and male impotence is amenable to the same treatment (e.g. especially using vasodilating agents such as S-nitrosothiols)..

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General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

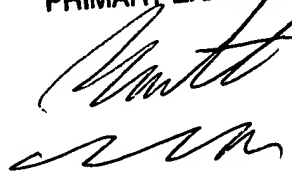
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

June 27, 2001

**BENNETT CELSA
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Bennett Celsa', is written over the printed name and title.